

Patent Appln. No. 10/828,439
Atty. Docket No. PC19450D

REMARKS

Preliminary Matter

Initially, Applicants wish to correct statements made at pages 8-9 of the Amendment and Response filed 15 July 2005. Daptomycin is not a glycopeptide, but is understood to actually be a lipopeptide.

Status of the Claims

The Office Action mailed 31 Aug 2005 rejects all of the then pending claims (claims 1-11). Claims 12-66 had previously been canceled. Claims 1-11 are now canceled without prejudice or disclaimer. New claims 67-81 are now presented for examination.

Response to Obviousness Rejection

Claims 1-11 are rejected under 35 USC § 103(a) over US Patent No. 5,750,509 to Malabarba et al. ("MALABARBA"). The rejection states that MALABARBA discloses dalbavancin in combination with a stabilizer and in particular with lactose or sorbitol. The rejection states that MALABARBA does not disclose the pH being about 3-5 but that varying the pH of a pharmaceutical composition is purportedly within ordinary experimentation by the skilled artisan. Thus, the rejection concludes that the claims are obvious. The rejection finds Applicants' previous arguments unpersuasive.

Applicants respectfully traverse the rejection. As discussed below, Applicants submit that MALABARBA does not render the claimed invention unpatentable, and, moreover, that the skilled artisan would not be motivated by the general skill in the art to modify MALABARBA as proposed. Furthermore, Applicants' dependent claims recite numerous additional features not in the base claim and not disclosed or suggested in the applied art.

The present claims provide a stabilized dry dosage form for reconstitution comprising dalbavancin with an effective stabilizer comprising a sugar, wherein the pH of the dosage form is about 3 to about 5. Applicants also direct the Examiner's attention for close consideration of the dependent claims, which recite various significant features such as specific stabilizer components, stabilizer ratios, multimer content, and pH.

Although MALABARBA states that a stabilizer may be used, the document does not teach or suggest how to successfully stabilize dalbavancin. That is, MALABARBA suggests stabilizing dalbavancin, essentially without more. Respectfully, reliance on the mention of lactose and sorbitol is misplaced, as these compounds are listed generically as conventional excipients. As a result, in order to attain what the rejection proposes, the skilled artisan intending to stabilize dalbavancin in view of MALABARBA, would be left to (1) specifically

select the particular sugars cited in the rejection as *stabilizers* from the list of "conventional excipients", and (2) use them in an appropriate manner and amounts. However, there is no motivation in MALABARBA to select these sugars from the excipients for this purpose because they are not disclosed as stabilizers, nor is there any teaching or suggestion therein to stabilize dalbavancin therewith.

In addition, the rejection relies on the ordinary skill in the art without citation to any reference for both (1) the specific pH range recited in the claims, and (2) the motivation to combine the pH feature with MALABARBA. Respectfully, this application of asserted ordinary skill is overreaching, especially given the limited nature of certain aspects of MALABARBA, discussed above. First, taking official notice of facts outside the record should be limited to wherein the asserted facts are capable of instant and unquestionable demonstration as being well known. See, e.g., *In re Beasley*, 117 Fed. Appx. 739 (Fed. Cir. 2004) (citing *In re Ahlert*, 165 USPQ 418, 420 (CCPC 1970)). Applicants submit that an assertion that varying pH *per se* is well known is too broad to be accepted as well known, much less accepted as being applicable for combination with the MALABARBA subject matter. Moreover, the rejection does not assert that the asserted knowledge of varying pH is known to universally be used with sugar stabilizers and glycopeptides including dalbavancin. Thus, even under the facts asserted in the rejection, there is no motivation to combine varying the pH with MALABARBA, much less with the claimed sugar stabilizers. See, e.g., *In re Lee*, 277 F.3d 1338, 1343-44 (Fed. Cir. 2002) (reversing a rejection lacking a reference to support motivation).

Applicants further note that it has been determined that dalbavancin pH is a factor in the ratio of dalbavancin multimer to monomer, which in turn can affect administration of dalbavancin. Please see, e.g., pp. 53-54 and Fig. 5 of the specification. There is no suggestion in the applied art of providing the claimed invention, including the recited stabilizer and pH, including stabilizing a higher proportion of multimer.

The dependent claims are patentable over the applied art on still additional grounds. For example, there is no teaching or suggestion in the applied art of using mannitol, of using mannitol in combination with lactose, of the recited stabilizer ratios, or the more specific pH recitations.

Conclusion

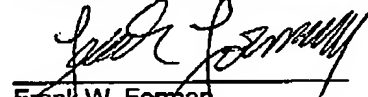
In view of the above, Applicants respectfully submit that the pending claims are allowable in their present form, and that the application is otherwise in condition for allowance. The Examiner is respectfully requested to withdraw the rejection and, as the next official action, to provide a Notice of Allowance.

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If any issues remain which can be resolved by a telephone conference, or should the Examiner have any questions or comments regarding this matter, the Examiner is respectfully invited to contact the undersigned at the telephone number shown below.

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Respectfully submitted,



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